Remarks

Claims 23-44 are in the case. All claims stand rejected. Applicant traverses the grounds of rejection. Clam 37 has been amended to delete material that was inadvertently included in the previous version of claim 37. Entry of the amendment is respectfully requested.

As requested by the Examiner, applicant specifies that it first began offering the claimed apparatus for sale in June 2003.

Claim Rejections - 35 USC § 103

Claims 23 - 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen et al. (US 2003/0180262 Al).

The Examiner takes the position that Muschler teaches a bone graft material, apparatus and method for making a bone graft material having various characteristics of the claimed invention. The Examiner admits that Muschler does not teach the methods or apparatus wherein air is expelled. However, the Examiner takes the position that Wironen teaches methods and apparatuses for making bone graft composites wherein the air is expelled from the tube containing the bone material, citing Wironen ¶ 0022, 0034, 0043, 0045. According to the Examiner, Wironen teaches that it is typically desirable to remove air from the paste components before, during or after reconstitution is conducted, citing Wironen ¶ 0045. The Examiner concludes that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to ensure that air is expelled since the reference teaches the desirability to do so. Moreover, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to remove any air from the apparatus of Muschler, as guided by Wironen. The Examiner admits that the reference does not specifically identify each of the claimed limitations, but relies on applicant's previous admission, made in response to a five-way restriction requirement, that each of the instant inventions are obvious over each other within the meaning of 35 USC 103. The Examiner concludes that because of applicant's admission, it would have been obvious to one of ordinary skill in the art to make, use and practice the claimed inventions as disclosed by Muschler and allegedly admitted by applicant. Notably, the Examiner does not attempt to explain how applicant's admission renders the claims obvious.

Applicant has several objections to the Examiner's reliance on applicant's admission. First, applicant respectfully submits that applicant's admission, which was made in response to the five-way restriction requirement, is being taken out of context and is now moot. Second, in relying on applicant's admission, the Examiner appears to be losing sight of the determinative issue of obviousness. Third, the Examiner has made no attempt to explain how applicant's admission renders the claimed invention obvious over the cited art.

In the response filed September 1, 2006, applicant elected to pursue a single set of claims, rather than five sets, and stated: "Applicant withdraws its prior statement that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103." The Examiner takes the position that applicant's admission cannot be expunged from the record. Applicant suggests that applicant's admission should be considered in the context in which it was made, and that this context is now moot. Applicant's admission concerning obviousness was made in response to a five-way restriction requirement involving five sets of claims that were very similar to one another. Because the five claim sets were very similar, applicant was of the view that the Patent Office had not met its burden of establishing that the application claimed five independent and distinct inventions. Rather than traverse the restriction requirement, applicant elected to admit that the claims were obvious over each other so that all five sets of similar claims could be examined in the same application. In particular, applicant stated:

> In view of the similarity in the structure and elements of the claims and applicant's concern that a showing of distinctiveness has not been made, applicant admits that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103. Therefore restriction between Inventions I, II, III, IV and V should not be required. See MPEP § 803; *In re Lee,* 199 USPQ 108 (Comm'r Pat. 1978).

After receiving the first office action, applicant elected to cancel the original five sets of very similar claims and proceed with a single set of claims. Applicant does not now seek to "expunge" the admission from the record, but rather is of the view that the statement is moot now that applicant has elected to pursue a single set of claims. The Examiner cites no legal basis as to why applicant cannot withdraw the earlier admission.

However, even if applicant is not permitted to withdraw the statement, which applicant obviously disputes, the Examiner has made no effort to explain how the admission renders obvious the claimed invention. Instead, the Examiner simply stated:

> The reference does not specifically identify each of the claimed limitations. However, in the reply filed on March 14, 2006, applicant has clearly admitted on record that each of the instant inventions are obvious over each other within the meaning of 35 USC 103. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to make, use and practice the claimed inventions as disclosed by Muschler and admitted by applicant.

It is respectfully suggested that the foregoing merely states a conclusion, and is not sufficient to establish a prima facie showing of obviousness. Most importantly, the foregoing statement does not provide applicant with enough information to adequately respond to the Examiner's contention that applicant's admission renders the claims obvious. As MPEP ¶ 2142 makes clear, as part of the burden of making a prima facie showing, the Examiner must present reasoning supporting the obviousness rejection. When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). As the Federal Circuit stated in *In re Oetiker*, 977 F.2d 1443, 24 USPQ.2d 1443, 1447 (Fed. Cir. 1992):

> [T]he examiner cannot sit mum, leaving the applicant to shoot arrows in the dark hoping to somehow hit a secret objection harbored by the examiner. The "prima facie" case notion . . . seemingly was intended to leave no doubt among examiners that they must state clearly and specifically any objections (the prima facie case) to patentability, and give the applicant fair opportunity to meet those objections with evidence and argument.

In the present case, applicant respectfully suggests that it has not been given a sufficient explanation, and under the current record, does not have enough information to attempt to counter the Examiner's position that applicant's admission renders the claims obvious. Applicant requests clarification and withdrawal of final rejection status so that applicant can undertake a meaningful analysis of the Examiner's position.

By focusing on applicant's admission, the Patent Office appears to be losing site of the determinative issue. The question is not whether the current claims are obvious over the original claims, but whether they are obvious over the cited prior art, particularly in view of the Examiner's acknowledgement that the cited references do not teach all elements of the claimed invention. The central question is whether it would have been obvious to a person of ordinary skill in the art to combine the teachings of Muschler and Wironen to arrive at the claimed invention. Under § 103(a) and applicable case law, it is the Examiner's burden to demonstrate that the cited references provide a suggestion, motivation or teaching to arrive at the claimed invention. Instead, without explaining how the previous admission renders the claims obvious, the Examiner simply states that applicant's admission renders the claims obvious.

With regard to the obviousness showing under Muschler and Wironen, applicant reiterates is previous position concerning the absence of a prima facie showing of obviousness. As previously stated, the current claims are directed more specifically to an apparatus that applicant has been selling successfully. In actual practice, applicant has found that a bone marrow aspirate impermeable filter member on the second or leading end of the tube is an important feature because it enables the tube to be filled with as much bone marrow aspirate as possible, which in turn exposes the bone graft material to as much bone marrow aspirate as possible. Without a filter, the bone marrow aspirate simply flows across the bone graft material, and consequently the bone graft material can only absorb bone marrow aspirate components that flow past the bone graft material. Fluid pressure created in the tube during expulsion of air through the filter creates back flow, which further circulates bone marrow aspirate within the bone graft material. With the filter on the leading end of the tube, all of the bone marrow aspirate is retained and, after a selected period of coagulation, a more uniformly shaped piece of composite bone graft material is obtained. The foregoing features are particularly useful in the operating room, because they enable formation of a composite bone marrow aspirate bone graft material using relatively simple instruments and methods, and within a time frame suitable to surgical procedures. The claimed apparatus enables the foregoing functions.

It is respectfully suggested that a prima facie case of obviousness has not been established. As the Examiner has admitted, the cited reference does not specifically identify each of the claimed limitations. There is a gap in the teachings of the cited Muschler and Wironen references, and applicant respectfully suggests that when the cited references are carefully studied, they do not provide the required suggestion or teaching necessary to fill the gap.

As previously noted, nothing in Muschler suggests the need to remove air from the Muschler enriched bone graft, much less the need to remove air while preventing passage of bone marrow aspirate. Muschler specifically teaches away from this aspect of the claimed invention in at least two fundamental ways: (1) Muschler describes a screen or membrane that allows bone marrow aspirate to pass through Muschler's matrix material; and (2) the objective of Muschler is to provide a composite bone marrow graft material having an enriched population of progenitor cells.

With regard to Muschler's screen or membrane, Muschler states: "Optionally, endcaps 14 can be provided with a screen or membrane 15 (see FIG. 8) *effective to allow aspirate 20 to pass therethrough*, while retaining particles of matrix 10." (Muschler, Col. 7, lines 15-17; emphasis added). The only other place where Muschler mentions the membrane 15 is at Col. 10, lines 47-49, where Muschler states simply: "Optionally, the kit is provided with a porous biocompatible implanted substrate for use as a bone graft matrix, and porous membranes 15 to retain a matrix within the matrix container." Thus, Muschler describes the membrane as being configured to ***allow bone marrow aspirate to pass therethrough***, and ***nowhere does Muschler suggest the need to configure the membrane to prevent passage of bone marrow aspirate while allowing passage of air***.

Removing air while retaining bone marrow aspirate in the container runs counter to the very purpose of Muschler, which is to produce a "composite bone marrow graft material [having] an enriched population of progenitor cells." (Muscler, Col. 2, lines 40-41). Key distinctions between Muschler and the claimed invention are highlighted at Muschler Col. 7, lines 39-Col. 8, line 11. Muschler specifically describes a process in which the bone marrow aspirate passes entirely through the matrix 10 in order to create the enriched graft material: "First loading syringe 28 is then plunged, delivering aspirate 20 into column 12 where aspirate 20 flows through or contacts matrix 10 *prior to being collected at the opposite end of column 12 in second loading syringe 29*." (Col. 7, lines 39-42; emphasis added). Muschler describes how the process of flowing the bone marrow aspirate through the matrix 10 results in an enriched graft: "Progenitor cells advantageously and selectively adhere to the surface of matrix 10, and hence are retained within the matrix while excesses of other cells, such as blood cells and other marrow-derived nucleated cells, flow relatively freely through the matrix and are collected in second loading syringe 29." (Col. 7, lines 48-53). According to Muschler, after using the Muschler process of flowing the aspirate through the matrix, the resulting graft contains between a 2 to 8 fold increase in the ratio of progenitor cells compared to natural bone marrow aspirate. (Col. 7, line 61-Col. 8, line 3).

In distinct contrast with Muschler, applicant's claims are directed to a tube that allows for expelling air from the tube while retaining the bone marrow aspirate in the tube. When all of the bone marrow aspirate is retained in the tube, the ratio of progenitor cells to natural bone marrow aspirate does not change. Thus, the use of applicant's claimed tube will not result in a matrix having an increased ratio of progenitor cells. Thus, if Muschler were modified to include a filter that allowed air to pass through while retaining bone marrow aspirate, the stated function of Muschler (to increase the ratio of progenitor cells) would be destroyed.

In ¶0026 of applicant's specification, applicant discussed the foregoing features of Muschler with reference to Muschler's U.S. Patents 5,824,084 and 6,049,026. After explaining the foregoing features of Muschler, applicant noted that applicant's invention "offers flexibility by allowing the composite to be mixed (i.e infused) in the operating room . . . using the patient's own healing potential in the form of bone marrow aspirate, blood, or platelet concentrate." (Applicant's specification, ¶0027). As a key feature of applicant's apparatus, applicant noted: "The filter on the second end of the tube allows air to be expelled from the tube as it is filled with the bone marrow aspirate. However, the filter should be sufficiently dense to prevent leakage of the bone marrow aspirate." (*Id.* at ¶0028). Thus, directly counter to the teaching of Muschler, applicant teaches providing a filter on the second end that does not allow bone marrow aspirate to pass through. The teaching to provide such a filter and the resulting function is provided in applicant's specification, not in the cited prior art.

In combining the teachings of Muschler and Wironen to support a showing of obviousness, the Examiner notes that Wironen teaches methods and apparatuses for making bone graft composites wherein the air is expelled from the tube containing the bone material, citing ¶¶ 0022, 0034, 0043, and 0045 of Wironen. The Examiner takes the position that Wironen teaches that it is typically desirable to remove air from the paste components before, during or after reconstitution is conducted, citing Wironen ¶0045. The Examiner concludes that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to ensure that air is expelled since the reference clearly teaches the desirability to do so, and further, that it would have been obvious to one of ordinary skill in the art to remove any air from the apparatus of Muschler, as guided by Wironen.

In contrast with Muschler, Wironen makes no mention of the use of a bone marrow aspirate. Consequently, Wironen makes no suggestion of the desirability of retaining bone marrow aspirate while expelling air. Rather, Wironen is concerned with the problem of preserving and storing bone pastes. As explained in ¶0003 of Wironen, "While current methods of utilizing bone paste have shown promise, there is a constant need for devising new, cost-effective techniques of storing and preserving bone paste and other biomedical substances, which, in turn, will increase their usefulness and adaptability to medical applications." The preservation and storage of bone pastes is a different function than that of creating a useful bone marrow aspirate derived bone graft material.

In the few places where Wironen discusses the expulsion of air from a syringe, there is no suggestion that expulsion of air can be used to improve the process of forming a composite bone graft material from bone marrow aspirate. Of the four places where Wironen mentions "air," only one place describes expelling air from the syringe. ¶0022 is merely a brief description of drawing Figure 10. ¶0034 is concerned not with expelling air but rather with minimizing "dead" space between the two syringes, thereby alleviating unwanted air bubbles. Thus, ¶0034 is concerned with minimizing air bubbles rather than expelling air. ¶0043 describes a relatively complicated method of removing air from a bone paste using three syringes joined by a three-way stop valve. ¶0045 provides a detailed description of Figure 10, which depicts a syringe in which removal of air is facilitated by providing an aperture in the plunger of the syringe. In Wironen Figure 10, the plunger 1000 has an aperture 1010 at its end 1020 in contact with paste components, wherein the aperture communicates with the other end of the plunger 1030 through a channel 1040 defined within the plunger 1000. Preferably, to prevent escape of paste components or reconstitution fluid, the aperture is covered with an air-permeable membrane or filled with an air-permeable plug. As the plunger is pushed against the contents of the syringe, the pressure caused thereby acts to push the air contained in the contents through the aperture and expelled out of the syringe. (See Wironen, ¶0045). The structure of Wironen Figure 10 differs significantly from that of the claimed invention. Notably absent from Wironen is any suggestion or teaching of the desirability of retaining bone marrow aspirate while expelling air.

Considering all of the foregoing, it is respectfully submitted that a prima facie case of obvious has not been established. The cited references lack the required suggestion or teaching necessary to arrive at the claimed invention. Combining the references in the manner suggested by the Examiner would destroy the stated function of Muschler, which is to provide a bone graft having an enriched population of progenitor cells by passing bone marrow aspirate through a matrix. Applicant's specification is being used to supply the required suggestion to combine, resulting in hindsight reconstruction of the claimed invention.

Reconsideration and a notice of allowance are respectfully requested. It is believed that this response has been filed within the applicable time period for responding and that no extension of time is therefore required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no fees are due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,

/Shawn D. Sentilles/
Shawn D. Sentilles, Reg. No. 38,299
WRIGHT MEDICAL TECHNOLOGY, INC.
(USPTO Customer No. 37902)
5677 Airline Road
Arlington, TN 38002
Telephone: 901-867-4314

Dated: January 30, 2007